REMARKS

In the Office Action mailed July 3, 2006, the claims were subjected to a 25-way restriction, with the Examiner contending that the claims contain 25 separate and patentably distinct inventions. In addition to the 25-way restriction, the Examiner is further requiring an election within each restriction group.

Applicants traverse this requirement and request reconsideration of the restriction for the reasons set forth below.

Foremost, Applicants note that previous restriction as applied in the parent case, now US Patent No. 6,610,529, which was subject to the same restriction standards as allegedly being applied by the Examiner of the present case, contained **two** groups of invention in Applicants' application. Applicants are puzzled by the discrepancy in which the product claims, once considered to belong to one restriction group, are now found to include 19 separate invention groups.

Introduction

The disclosure, in its broadest sense, relates to environmentally limited viability systems (ELVS) for microbes based on differences in environmental conditions, i.e., permissive and non-permissive environments. Viability of the microorganisms is limited to the permissive environment by specifically expressing one or more essential genes while only in the permissive environment, and/or expressing one or more lethal genes only in the non-permissive environment. Alternatively, a "temporarily viable/delayed death" system may be achieved by temporarily expressing one or more essential genes in a non-permissive environment, and/or temporarily delaying expression of one or more lethal genes in the non-permissive environment. (*See, e.g.*, page 6, lines 1-12 of the specification.)

Restriction

In support for the 19-way restriction of the product claims in Applicants' application, the Examiner reasons:

> "Inventions I-XIX are related as products. The claims are drawn to microbial cells containing various combinations of essential, lethal, regulatory, and expression genes. The inventions are patentably distinct products because they are made by different methods and because they are physically functionally distinct entities with different biochemical and immunological properties." (Office Action, page 6.)

Applicants note that the Examiner, in stating that the products are related, admits that the product claims specified in restriction groups I-XIX are not independent. MPEP §808.02 controls the restriction of related inventions and MPEP §806.05(j) specifically controls the restriction of related products. MPEP §806.05(j) states:

> **"§ 806.05(j) Related Products; Related Processes**
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> To support a requirement for restriction between two or more related product inventions, or between two or more related process inventions, both two-way distinctness and reasons for insisting on restriction are necessary, i.e., separate classification, status in the art, or field of search. See MPEP § 808.02. See MPEP § 806.05(c) for an explanation of the requirements to establish two-way distinctness as it applies to inventions in a combination/subcombination relationship. For other related product inventions, or related process inventions, the inventions are distinct if
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> (A) the inventions *as claimed* do not overlap in scope, i.e., are mutually exclusive;
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> (B) the inventions *as claimed* are not obvious variants; and
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> (C) the inventions *as claimed* are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 802.01.
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> The burden is on the examiner to provide an example to support the determination that the inventions are distinct, but the example need not be documented. If applicant either proves or provides convincing evidence that the example suggested by the examiner is not workable, the burden is on the examiner to suggest another viable example or withdraw the restriction requirement."

Applicants note that the Examiner's reasons for restriction of the product claims do not fall within the three categories of proper restriction of related product claims as specified above. The Examiner stated:

> "The inventions are patentably distinct products because they are **made by different methods** and because they are **physically functionally distinct entities** with **different biochemical and immunological properties**."

Applicants note that the form paragraph for which the MPEP section the Examiner apparently relies on for support actually states:

> **P 8.14.01 Distinct Products or Distinct Processes**
>
> Inventions **[1]** and **[2]** are directed to related **[3]**. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, **[4]**.

Applicants direct the Examiner to MPEP §806.05(j) and note that products as claimed overlap and are capable of use together, e.g., Claim 1 specifies microbes with environmentally limited viability systems comprising the regulation of an essential gene and/or a lethal gene. Moreover, the regulation of this essential gene and/or lethal gene can be regulated by the gene product of a regulatory gene. The product claims restricted into Groups I-XIX are not mutually exclusive but rather interrelated. Nor do the product claims subject to restriction contain materially different designs, modes of operation, functions, or effects – they are all environmentally limited viability systems (ELVS) for microbes based on differences in environmental conditions, i.e., permissive and non-permissive environments. Viability of the microorganisms are limited to the permissive environment by specifically expressing ore or more essential genes while only in the permissive environment, and/or expressing one or more lethal genes only in the non-permissive environment.

Furthermore, Applicants note that the Examiner has failed to establish *why* there would be a serious burden on the Examiner if restriction is not required. MPEP § 808.02 states:

> "**§ 808.02 Establishing Burden**
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> Where the related inventions as claimed are shown to be independent or distinct under the criteria of MPEP § 806.05(c) --> § 806.06, the examiner, in order to establish reasons for insisting upon restriction, must explain why there would be a serious burden on the examiner if restriction is not required. Thus the examiner must show by appropriate explanation one of the following:
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> (A) **Separate classification thereof**: This shows that each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Patents need not be cited to show separate classification.

(B) **A separate status in the art when they are classifiable together**: Even though they are classified together, each invention can be shown to have formed a separate subject for inventive effort when the examiner can show a recognition of separate inventive effort by inventors. Separate status in the art may be shown by citing patents which are evidence of such separate status, and also of a separate field of search.

(C) **A different field of search**: Where it is necessary to search for one of the inventions in a manner that is not likely to result in finding art pertinent to the other invention(s) (e.g., searching different classes/subclasses or electronic resources, or employing different search queries, a different field of search is shown, even though the two are classified together. The indicated different field of search must in fact be pertinent to the type of subject matter covered by the claims. Patents need not be cited to show different fields of search.

Where, however, the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among independent or related inventions." (Emphasis added.)

Applicants note that Restriction groups I-XIX all belong to class 435, subclass 252.3, and the Examiner has not provided evidence suggesting that the products have acquired a separate status in the art.

Conclusion and Provisional Election

Applicants submit that in view of the foregoing remarks all the claims are seen to relate to a single inventive concept, and the claims, particularly the product claims, are in a form and are of the sort that is properly viewed as relating to a single invention that should not be restricted. Applicants request that the restriction requirement of the Office Action of July 3, 2006 be reconsidered and withdrawn.

Although, for reasons set forth above, Applicants believe that the restriction is improper and uncalled for, and without in any way acquiescing in the reasons for the requirements set forth in the Office Action, but in order to be fully responsive to the Office Action, Applicants provisionally elect for examination the claims of Group 1, i.e., Claims 61-64, 67, 70-73, 76, 83-94 and 104-107. Applicants further elect *asd* as the essential gene and that the essential gene is *extrachromosomal*.

Respectfully submitted,

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date

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